Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (currently amended) An assaying method for detecting a prion disease in an animal or a human, the ~~assay~~ method comprising the steps of:

(a) homogenizing a biological sample from an animal or a human with a buffer;

(b) providing a test device ~~having~~ comprising:

(i) a digestive pad comprising immobilized proteinase-K ~~immobilized on a support~~;

(ii) a membrane through which the homogenized sample substantially free of nonpathogenic prion protein migrates by capillary action, the membrane being in fluid communication with the proteinase-K support; and

(iii) a pair of antibodies to the pathogenic prion protein, one of the antibodies being immobilized on the membrane, and the other of the antibodies being labeled for forming a complex with the pathogenic prion protein such that the complex migrates toward the immobilized antibody;

(c) applying the homogenized biological sample to the test device ~~so~~ wherein:

(i) the proteinase-K removes interfering constituents, and

(ii) the pathogenic prion protein in the sample binds with both antibodies to produce a response; and

(d) interpreting the response to indicate the presence or concentration of the pathogenic prion protein in the sample.

2. (original) The assay of claim 1 wherein the prion being analyzed causes a condition selected from the group consisting of transmissible spongiform encephalopathy (TSE) in bovine, sheep, and goats; scrapie in sheep and goat; transmissible mink encephalopathy (TME) in mink; chronic wasting disease (CWD) in mule deer and elk; feline spongiform encephalopathy in cats; and kuru, Creutzfeld-Jakob-disease (CJD), German-Straussler-Scheinker syndrome (GSS), and fatal familial insomnia (FFI) in humans.

3. (original) The assay of claim 1 wherein the biological sample is selected from brain tissue, whole blood, serum, plasma, saliva, urine, and cerebral spinal fluid.

4. (currently amended) The assay of claim 1 wherein the buffer in the homogenizing step extracts prion protein from the biological sample and the buffer comprises at least one emulsifier or surfactant, casein, at least one polysaccharide, albumin, and a sufficient quantity of water to form a mixture.

5. (currently amended) The assay of claim 4 wherein the emulsifier or surfactant is selected from octoxynol, nonoxynol, polyglycol ether, ~~polyoxythylene~~ polyoxyethylene (10) isooctylphenyl ether, sodium dodecyl sulfate , and sodium deoxycholate.

6. (original) The assay of claim 1 wherein the buffer is an aqueous solution with an ionic strength of from about 200 to about 400 mM.

7. (original) The assay of claim 1 wherein the response is read visually.

8. (original) The assay of claim 1 wherein the response is produced within from about 0.5 to about 20 minutes after the sample is applied to the test device.

9. (original) The assay of claim 1 wherein the response is produced within from about 5 to about 10 minutes after the sample is applied to the test device.

10. (original) The assay of claim 1 wherein the interpreting step comprises comparing the response to known responses to determine the concentration of the pathogenic prion protein.

11. (currently amended) An assay for determining the presence of pathogenic prion protein in a biological sample, the assay comprising:

(a) preparing a sample for analysis;

(b) providing a test device having:

a digestive pad having proteinase-K immobilized therein for removing nonpathogenic prion protein from the biological sample;

a conjugate pad having a labeled first antibody of an antibody pair to the pathogenic prion protein; and,

a test strip having an immobilized second antibody of the antibody pair for producing a response indicative of the presence or concentration of the pathogenic prion protein; the conjugate pad being disposed between the digestive pad and the test strip;

(c) applying the prepared sample to the test device so the sample is treated with proteinase-K and the pathogenic prion protein in the sample binds with both antibodies to produce a response; and

(d) ~~interpreting~~ determining the ~~response to indicate the~~ presence or concentration of the pathogenic prion protein in the sample based on the response.

12. (original) The assay of claim 11 wherein the preparing step comprises homogenizing the sample with a buffer to extract prion protein into the buffer medium.

13. (original) The assay of claim 11 wherein the preparing step comprises extracting prion protein into an aqueous buffer medium.

14. (original) The assay of claim 11 wherein the proteinase-K is immobilized on a support selected from latex beads, rod-shaped bodies coated with latex, micro- or nanoparticles, and a porous membrane pad.

15. (original) The assay of claim 11 wherein the proteinase-K is in a gelled substance contained in the digestive pad.

16. (currently amended) The assay of claim 11 wherein the proteinase-K immobilized on the support ~~is sufficient to digest~~ digests substantially all the nonpathogenic prion protein in the sample.

17. (original) The assay of claim 14 wherein the proteinase-K is immobilized on latex beads.

18. (currently amended) The assay of claim 11 wherein the amount of ~~enzyme~~ proteinase-K ~~on the solid support~~ ranges from about 30 micrograms to about 400 micrograms.

19. (original) The assay of claim 11 wherein the response is read visually.

20. (original) The assay of claim 11 wherein the sample preparing step comprises homogenizing the sample with a buffer in a weight/volume ratio of sample (mg) to buffer (ml) ranging from about 2:1000 to about 200:1000.

21. (original) The assay of claim 11 wherein the sample preparing step comprises homogenizing the sample with a buffer having an ionic strength ranging from about 200 to about 400 mM.

22. (original) The assay of claim 11 wherein the sample preparing step comprises homogenizing the sample with a buffer comprising at least one surfactant or emulsifier, at least one polysaccharide, casein, and albumin.

23. (currently amended) The assay of claim 22 wherein the at least one emulsifier in the buffer is selected from octoxynol, nonoxynol, polyglycol ether, ~~polyoxythylene~~ polyoxyethylene (10) isooctylphenyl ether, sodium dodecyl sulfate, and sodium deoxycholate.

24. (original) The assay of claim 22 wherein the at least one polysaccharide in the buffer is selected from sucrose, mannose, trehalose, and maltose.

25. (original) The assay of claim 22 wherein the at least one polysaccharide is used at a concentration ranging from about 0.1 to about 30 %, by weight of the buffer.

26. (original) The assay of claim 22 wherein the buffer further comprises a zwitterionic buffering agent.

27. (original) The assay of claim 11 wherein the response is read by instrumentation.

28. (currently amended) An assay for detecting the presence of pathogenic prion protein in foodstuffs, comprising:

(a) preparing a sample of foodstuff for analysis;

(b) providing a test device having:

(i) proteinase-K immobilized on a ~~support~~ support;

(ii) a membrane through which the sample migrates by capillary action, the membrane being in fluid communication with the proteinase support; and

(iii) a pair of antibodies to the pathogenic prion protein including an antibody immobilized on the membrane and a labeled antibody.

(c) applying the prepared sample to the test device for ~~enzymatic treatment and~~ immunochromatographic binding of the pathogenic prion protein to produce a response; and

(d) ~~interpreting~~ determining the ~~response to indicate the~~ presence or concentration of the pathogenic prion protein in the sample based on the response.

29. (original) The assay of claim 28 wherein the sample preparing step comprises homogenizing the sample with a buffer in a weight/volume ratio of sample (mg) to buffer (ml) ranging from about 2:1000 to about 200:1000.

30. (original) The assay of claim 28 wherein the sample preparing step comprises homogenizing the sample with a buffer having an ionic strength ranging from about 200 to about 400 mM.

31. (original) The assay of claim 28 wherein the sample preparing step comprises homogenizing the sample with an aqueous buffer comprising at least one surfactant or emulsifier, at least one polysaccharide, casein, and albumin.

32. (original) The assay of claim 28 wherein the sample preparing step comprises homogenizing the sample with an aqueous buffer to extract prion protein into the buffer medium.

33. (original) The assay of claim 28 wherein the sample is animal feed.

34. (currently amended) The assay of claim 28 wherein the sample is ~~an~~ a consumable animal part ~~designated for human consumption~~.

35. (currently amended) An assay for pathogenic prion protein in foodstuffs, comprising:

(a) removing interfering constituents from a foodstuff sample by contacting the sample with proteinase-K immobilized on a support;

(b) applying the sample to a test device having

(i) a membrane; and

(ii) an antibody immobilized on the membrane; and

(iii) a labeled antibody that complexes with pathogenic prion protein in the sample and migrates through the membrane toward the immobilized antibody; and

(c) ~~obtaining a result indicative of~~ analyzing the test device for the presence or concentration of pathogenic prion protein in the foodstuff.

36. (original) The assay of claim 35 wherein the constituent-removing step is preceded by homogenizing the sample with a buffer.

37. (original) The assay of claim 36 wherein the buffer comprises at least one emulsifier or surfactant, casein, at least one polysaccharide, albumin, and a sufficient quantity of water to form a mixture.

38. (original) The assay of claim 36 wherein the buffer has an ionic strength of from about 200 to about 400 mM.

39. (original) The assay of claim 35 wherein prior to the constituent-removal step, the sample is homogenized with a buffer in a weight (mg)/volume (ml) ratio ranging from about 2:1000 to about 200:1000.

40. (currently amended) An assay for detecting the presence or concentration of pathogenic prion protein in a sample of biological material, the assay comprising:

(a) extracting prion protein from a biological sample into an aqueous buffer;

(b) applying the prion protein-containing buffer to a test device having:

(i) a membrane through which ~~the~~ a homogenized sample migrates by capillary action, the membrane being in fluid communication with ~~the~~ a proteinase support; and

(ii) a pair of antibodies with high affinity to pathogenic prion protein, including a labeled first antibody and a second antibody immobilized on the membrane, each of the antibodies specific to a different epitope of the pathogenic prion protein;

(c) allowing the pathogenic prion protein in the sample to bind with both antibodies to produce a test result; and

(d) interpreting the response to indicate the presence or concentration of the pathogenic prion protein in the sample.